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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,170	11/10/2000	Raymond P. Warrell	10412-025	4982

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/709,170	WARRELL ET AL.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 7-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, and 7-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Rescinded Abandonment

A Notice of Abandonment was filed and made of record only July 25, 2007. This Notice was sent in error. It this regard, the Notice of Abandonment mailed July 25, 2007 has been rescinded and the request for continued examination under 37 CFR 1.114, filed July 16, 2007 has been entered on the record as detailed below.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission mailed on July 16, 2007 has been entered.

Claims 6 and 29-33 have been canceled.

Claims 1, 3-5, 7-10, 12-16, and 19 have been amended.

Claims 1, 3-5, and 7-23 are pending in the instant application.

Claims 1, 3-5, and 7-23 have been examined on the merits.

Response to Arguments

Applicant's Amendment and Response mailed July 16, 2007 have been considered. Rejections and/or objections not reiterated from the previous office action

mailed November 28, 2006 are hereby withdrawn. Any arguments addressing said rejections and/or objections are moot. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Claim Rejections 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, and 7-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (The Lancet, 1997 Vol. 349:1137-1141, Applicant's reference CP on the Information Disclosure Statement filed February 23, 2001), in view

of Waters et al. (Journal of Clinical Oncology, 2000 Vol. 18:1812-1823, Applicant's reference CO on the Information Disclosure Statement filed February 23, 2001) and Bennett et al. [U.S. Patent No: 6,214,986], (made of record in the previous Office Action mailed July 26, 2004).

Claims 1, 3-5, and 7-17 are drawn to a method of treating cancer in a human comprising administering a bcl-2 antisense in more than one cycle of therapy, each cycle of therapy consisting of 3 to 9 days, wherein each cycle of therapy is separated by an interval of time wherein said human receives no bcl-2 antisense oligonucleotide, and wherein said interval of time comprises at least one day, and further comprises administering one or more cancer therapeutics. Claim 18 is drawn to a specific bcl-2 antisense oligonucleotide comprising SEQ ID NO:17. Claims 19-23 are drawn to a method of treating cancer in a human comprising administering a bcl-2 antisense in more than one cycle of therapy, each cycle of therapy consisting of 3 to 9 days, in combination with a chemoagent, wherein each cycle of therapy is separated by an interval of time wherein said human receives no bcl-2 antisense oligonucleotide, and wherein said interval of time comprises at least one day.

Webb et al. teach bcl-2 antisense therapy at a dose from 4.6 mg/m^2 to 73.6 mg/m^2 in human patients with non-Hodgkin lymphoma (see Abstract). Specifically, Webb et al. disclose the reduction of bcl-2 protein levels in the lymph node aspirates of Patient 6 after a 7 day course of therapy using a fully phosphorothioated bcl-2 antisense administered to Patient 6 (see Figure 2). It is noted that the fully phosphorothioated bcl-2 antisense oligonucleotide disclosed by Webb et al. is 100% identical to SEQ ID NO:17

of the instant invention. Webb et al. are silent regarding whether cancer was treated in Patient 6 after the 7-day course of bcl-2 antisesne oligonucleotide treatment. However, since the instant claims are drawn to a method of treating cancer in a human comprising one step, namely the administration of a bcl-2 antisense for 3 to 9 days, and Webb et al. disclose the 7-day administration of a bcl-2 antisense oligonucleotide in Patient 6, it is the Examiner's position that at day 7, the cancer in Patient 6 was inherently treated since the method disclosed by Webb et al. is fully embraced in the method as instantly claimed.

Because Webb et al. are silent regarding whether cancer was treated in Patient 6 following the 7-day course of bcl-2 antisense oligonucleotide treatment, the burden of establishing whether the teachings disclosed by Webb et al. would have the additional function of treating cancer under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: **"[T]he PTO can require an**

Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594. 596, (CCPA 1980), quoting In re Best 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the administration of a bcl-2 antisense oligonucleotide to Patient 6 for 7 days disclosed by Webb et al. would or would not treat cancer as instantly claimed.

The Examiner would like to point out that She is not arguing that a reduction in bcl-2 levels is considered to be evidence of cancer treatment. Instead, the Examiner is arguing that since Webb et al. teach the only method step recited in the instant claims, the method disclosed by Webb et al. would inherently "treat cancer", absent evidence to the contrary.

Webb et al. do not teach more than one cycle of therapy separated by an interval of time wherein the human receives no bcl-2 antisense oligonucleotide, wherein said interval of time comprises at least one day, and wherein said therapy further comprises administering one or more cancer therapeutics or chemoagents and at specific doses.

Waters et al. teach interrupted bcl-2 antisense oligonucleotide therapy in patients with non-Hodgkin's lymphoma for the purpose of monitoring drug toxicity, treatment efficacy, and response. For example, Waters et al. teach that one course of treatment was planned per patient, but additional courses of treatment were considered in the event of a tumor response (see page 1813, first column). Waters et al. also teach a second course of treatment administered to Patients no. 2, 17, and 21, where Patient

17, for example, was retreated after 48 hours of his initial course of therapy (see page 1813, first column and page 1818, second column).

Bennett et al. teach the antisense modulation of bcl expression using therapeutic compositions comprising antisense oligonucleotides. Bennett et al. also teach bcl antisense oligonucleotides are administered with one or more cancer therapeutics that function by a non-antisense mechanism, including doxorubicin, 5-fluorouracil (5-FU), etoposide, and cisplatin, for example (see column 16, lines 28-52). Bennett et al. teach "the formulation of therapeutic compositions and their subsequent administration is believed to be within the skill of those in the art. Dosing is dependent on severity and responsiveness of the disease state to be treated, with the course of treatment lasting from several days to several months, or until a cure is effected or a diminution of the disease state is achieved. Optimal dosing schedules can be calculated from measurements of drug accumulation in the body of the Patient. Persons of ordinary skill can easily determine optimum dosages, dosing methodologies and repetition rates. Optimum dosages may vary depending on the relative potency of individual oligonucleotides, and can generally be estimated based on EC_{50s} found to be effective in *in vitro* and *in vivo* animal models. In general, dosage is from 0.01 μg to 100 g per kg of body weight, and may be given once or more daily, weekly, monthly or yearly, or even once every 2 to 20 years. Persons of ordinary skill in the art can easily estimate repetition rates for dosing based on measure residence times and concentrations of the drug in bodily fluids or tissues" (see columns 16-17, last and first paragraphs, respectively).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to devise a method of treating cancer in a human comprising administering a bcl-2 antisense in more than one cycle of therapy, wherein each cycle of therapy consists of 3 to 9 days, wherein each cycle of therapy is separated by an interval of time wherein the human receives no bcl-2 antisense oligonucleotide, and wherein said interval of time comprises at least one day, using the teachings of Webb et al. and Waters et al. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer the antisense therapy further comprising administering one or more cancer therapeutics or chemoagents using the teachings of Bennett et al.

One of ordinary skill in the art would have been motivated to devise a method of treating cancer in a human comprising administering a bcl-2 antisense in a cycle of therapy consisting of 3 to 9 days since Webb et al. taught the reduction of bcl-2 protein levels in the lymph node aspirates of Patient 6 after the 7-day administration of a bcl-2 antisense oligonucleotide. One of ordinary skill in the art would have been motivated to devise a method of treating cancer in a human comprising more than one cycle of therapy separated by an interval of time wherein the human receives no bcl-2 antisense oligonucleotide, and wherein said interval of time comprises at least one day since Waters et al. taught bcl-2 antisense oligonucleotide interrupted therapy for the purpose of monitoring drug toxicity, treatment efficacy, and response. One skilled in the art would have been motivated to administer the antisense therapy further comprising administering one or more cancer therapeutics or chemoagents as taught by Bennett et

al. since it is routine and well known in the art that combination therapy is an effective approach for cancer treatment. One of ordinary skill in the art would have been motivated to vary the cycles of therapy or to vary the antisense dosage amount since it is routine and well known in the art to determine optimum dosages, dosing methodologies, and repetition rates based on measured residence times and concentrations of the drug in bodily fluids or tissues as taught by either Webb et al. or Bennett et al.

One of ordinary skill in the art would have expected success at devising a method of treating cancer in a human comprising administering a bcl-2 antisense in more than one cycle of therapy, wherein each cycle of therapy consists of 3 to 9 days, and wherein each cycle of therapy is separated by an interval of time wherein the human receives no bcl-2 antisense oligonucleotide, and wherein said interval of time comprises at least one day since Webb et al. taught the successful use of bcl-2 antisense therapy in a human for 3 to 9 days and Waters et al. taught interrupting the antisense therapy is well tolerated, has no systemic toxicity, and is still effective as a therapeutic. One of ordinary skill in the art would have expected success at administering the antisense therapy further comprising administering one or more cancer therapeutics or since Bennett et al. taught how to successfully use antisense compounds with one or more other chemotherapeutic agents which function by a non-antisense mechanism as a means to treat cancer.

Therefore the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's filing.

Response to Arguments

It is noted that a similar rejection was made of record in the previous Office Action mailed November 28, 2006. In response to this rejection, Applicants argue against both the Webb et al. and the Waters et al. references individually to conclude that, based on these references, one skilled in the art would not have been motivated to treat cancer in a human by shortening the cycles of therapy from a 2 week cycle of therapy to a cycle of therapy consisting of 3 to 9 days, followed by an interval of time where no bcl-2 antisense oligonucleotide is administered, followed by another 3 to 9 day cycle of therapy.

First, Applicants must consider the rejection based upon the combination of the references. See MPEP 2145 where it states, "One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references". In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding Webb et al., Applicants argue that there is no motivation to shorten the course of therapy to less than a two-week course of treatment. Applicant makes this argument based on the opinionated Declaration of Dr. Steven Craig Novick, filed July 16, 2007. Since Applicant's arguments are largely based on the Novick Declaration, the Examiner will address Applicant's arguments as they are detailed in the Novick Declaration.

The opinionated Declaration first argues that before the priority date of the instant application, the generally accepted course of therapy was a 14-day treatment regimen. To support this opinion, the Declaration points the Examiner to an exhibit attached as Tab A, filed July 16, 2007 in which the prior-art, as it relates to bcl-2 antisense protocols is summarized. The Declaration discusses that its was not until after the present inventor's discovery that a shorter cycle of therapy would be useful in treating cancer, did others move to a shorter cycle of therapy. To support this opinion, the Declaration points the Examiner to an exhibit attached as Tab B, filed July 16, 2007 in which the post-art, as it relates to bcl-2 antisense protocols is summarized.

The Examiner acknowledges and has considered the exhibits and agrees that, based on Tab A, at the time the invention was made, the generally accepted course of therapy was a 14-day treatment regimen. However, as discussed *supra*, Webb et al. disclose the reduction of bcl-2 protein levels in the lymph node aspirates of Patient 6 after a 7 day course of therapy. The Declaration acknowledges that Webb et al. reports the bcl-2 levels of Patient 6 measured at week 1 and week 2 during the course of a two-week course of treatment (see the Novick Declaration at page 3, #11). However, the Declaration is of the opinion that, based on these teachings, one skilled in the art would not have been motivated to treat a patient for cancer by shorting the regimen to less than the two week course of treatment since Patient 6 showed only a partial tumor response. Specifically, the Declaration is of the opinion that a reduction of bcl-2 levels at day 7 does not provide evidence of treatment or a response, nor motivation to shorten the treatment regimen because one skilled in the art would not know whether

this reduction represented a transient reduction or stable reduction. The Declaration contends that, based on Webb, one skilled in the art would be motivated to continue with a longer course of therapy, or change the regimen to a course of therapy with a higher dose, or add to the regimen a second, third, or fourth (or more) course of therapy, or a combination of all these changes to the regimen. It is because of this evidence that the Declaration is of the opinion that Webb does not teach or suggest changing the treatment regimen to anything shorter than a two-week course of therapy, let alone to a 3 to 9 day course of therapy as instantly claimed.

These opinions and contentions have been fully considered, but are not found persuasive. For the sake of clarity, the Examiner would like focus the reports of Webb et al. to the results and discussions of one particular Patient, Patient 6. As discussed *supra*, Webb et al. disclose the reduction of bcl-2 protein levels in the lymph node aspirates of Patient 6 after a 7 day course of therapy. The Novick Declaration acknowledges that Webb et al. reports the bcl-2 levels of Patient 6 measured at week 1 and week 2 during the course of a two-week course of treatment. Now then, it is noted that Webb et al. also report that, in Patient 6, bcl-2 levels are reduced at weeks 1 and 2, compared with pretreatment (see Figure 2); Patient 6 had a near partial response in tumor shrinkage, where a partial response has been defined as "a 50% or more reduction in the bidemsional product of measurable disease" (see page 1138, first column and Table 3); and Patient 6 had a reduction in the number of circulating lymphoma cells (see page 1139, second column, last few lines and Table 3).

It is the Examiner's position that, based on the results from Patient 6, one skilled in the art would have been motivated to shorten the generally accepted 14-day course of therapy to, for example, 7 days, since Webb et al. teach that at day 7, bcl-2 levels in the lymph nodes were reduced in Patient 6, compared with pretreatment. Because Patient 6 eventually exhibited evidence of tumor shrinkage and had a decrease in the number of circulating lymphoma cells, one skilled in the art would have been motivated to shorten the course of therapy to 7 days to determine whether this brief course of therapy was responsible for the favorable results seen in Patient 6. Furthermore, Webb et al. teach "[O]ur findings are encouraging and warrant further investigations of bcl-2 antisense therapy in cancer treatment" (see page 1137 @ Interpretations). Given this teaching, one skilled in the art would have been encouraged to further investigate bcl-2 antisense therapy to determine if shorter courses of therapy, including a course of therapy consisting of 7 days, would be a potential treatment option for the future. Thus, one skilled in the art, with the knowledge of Webb et al., would have been motivated to treat cancer in a human by shortening the cycles of therapy from the generally accepted 14-day cycle of therapy.

Regarding the opinion of the Declaration, that based on Webb, one skilled in the art would not have been motivated to treat a patient for cancer by shorting the regimen to less than the two week course of treatment since Patient 6 showed only a partial tumor response, this is not found persuasive. Applicant is reminded that the claims are drawn to a method of **treating** cancer in a human, not a method of **preventing** cancer in a human. Clearly, the disclosed reports of Webb et al. show evidence of reduction in

tumor size and tumor response in a human patient and thus constitute a method of treating cancer.

Regarding Waters et al., the Declaration argues that there is no motivation to shorten the course of therapy to less than a two-week course of treatment. The Declaration contends that Waters teaches discontinuing bcl-2 antisense oligonucleotide therapy due to reported toxic events in patients, and that stopping treatment due to adverse events does not teach or suggest using a shorter course of therapy to treat cancer. The Declaration summarizes the reports of two Patients, Patient 17 and Patient 18, and acknowledges that three Patients (Patient 2, 17, and 21) received a second course of therapy (see the Novick Declaration at page 5, #20). The Declaration contends that Patient 17 received two days of therapy, then treatment was discontinued because of dose limiting toxicity. The Declaration is of the opinion that although Patient 17 received a second course of therapy, there is nothing to teach or suggest that this course was anything but the planned 14-day cycle required by the protocol. The Declaration is of the opinion that Waters was not impressed with the results of the study and therefore did not contemplate a shorter treatment regimen, but instead proposed a combination therapy.

These opinions and contentions have been fully considered, but are not found persuasive. First, the Examiner agrees that stopping treatment due to adverse events and toxicities, as taught by Waters et al., does not teach or suggest using a shorter course of therapy to treat cancer. However, it is noted that the Waters et al. reference was not relied upon for teaching a shorter course of therapy to treat cancer in a human.

Instead, the Waters et al. reference was relied upon to teach interrupted bcl-2 antisense oligonucleotide therapy for the purpose of monitoring drug toxicity, treatment efficacy, and response. Applicant is reminded that the 103 rejection of record is based on combinations of references to arrive at the present invention as claimed. It is the teachings of Webb et al. combined with the teachings of Waters et al. and Bennett et al., and not the teachings of any one of these references alone that one skilled in the art would have been motivated to treat cancer in a human by shortening the cycles of therapy from the generally accepted 2 week cycle of therapy to a cycle of therapy consisting of 3 to 9 days, followed by an interval of time where no bcl-2 antisense oligonucleotide is administered, followed by another 3 to 9 day cycle of therapy. Clearly, Waters et al. teach that a patient is given a course of bcl-2 antisense therapy, followed by a rest period, followed by another course of bcl-2 antisense therapy. While Waters et al. may not teach that the course of therapy consists of 3 to 9 days as instantly claimed, as discussed *supra*, Webb et al. was relied upon to teach this aspect of the claimed invention.

Applicants finally argue that the Examiner has taken the present claimed invention and read back into the Webb and Waters reference to find an alleged motivation and has thus used hindsight reasoning to base the 103 rejection of record.

This argument has been fully considered, but is not found persuasive. It is noted that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed

invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, at the time the invention was made, Webb et al. taught the reduction of bcl-2 protein levels in the lymph node aspirates of Patient 6 after a 7 day course of therapy. Webb et al. also teach that in Patient 6, bcl-2 levels are reduced at weeks 1 and 2, compared with pretreatment; Patient 6 had a near partial response in tumor shrinkage; and Patient 6 had a reduction in the number of circulating lymphoma cells. Webb et al. also teach that further investigations of bcl-2 antisense therapy in cancer treatment are warranted. Based on the favorable results exhibited by Patient 6 following bcl-2 antisense therapy and the fact that Webb et al. suggest further investigations of bcl-2 antisense therapy in cancer treatment, one skilled in the art would have been encouraged to further investigate bcl-2 antisense therapy to determine if shorter courses of therapy, including a course of therapy consisting of 7 days, would be a potential treatment option for the future. Webb et al. do not teach stopping therapy for any period of time, then resuming therapy again. Waters et al. teach interrupting bcl-2 antisense therapy for the purpose of monitoring drug toxicity, treatment efficacy, and response. Specifically, Waters et al. teach a bcl-2 course of therapy, followed by an interrupted period, then followed by another course of therapy (see results for Patient 17, for example).

Therefore, based on the evidence of record, it is the Examiner's position that one of ordinary skill in the art, with the knowledge of Webb et al. combined with the knowledge of Waters et al., would have been motivated to treat cancer by shortening

the cycle of therapy from the generally accepted 14-day cycle of therapy to a cycle of therapy consisting of, for example, 7 days, followed by an interval of time where no bcl-2 antisense oligonucleotide is administered, followed by another cycle of therapy consisting of 7 days.

The Examiner would like to note and make of record that the PTO has required that Applicant prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product (see the discussion above at pages 5 and 6). In meeting their burden of providing evidence that the administration of a bcl-2 antisense oligonucleotide to Patient 6 for 7 days disclosed by Webb et al. would or would not treat cancer as instantly claimed, Applicant has only provided evidence in the form of the opinionated Declaration of Dr. Steven Craig Novick. Applicant is reminded that arguments of counsel alone cannot take the place of evidence in the record. See MPEP §2106. Applicant has not provided any evidence that the administration of a bcl-2 antisense oligonucleotide to Patient 6 for 7 days disclosed by Webb et al. did not treat cancer. Therefore, since Webb et al. teach the same methods steps as instantly claimed, namely, administering a bcl-2 antisense to a human patient for a cycle of therapy consists of 3 to 9 days (e.g. 7 days), it is the Examiner's position that Webb et al. meet all the limitations of the instant claims and would be expected to treat cancer, absent evidence to the contrary.

Conclusions

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg
August 19, 2007

/Terra Cotta Gibbs/